UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,137	07/23/2003	Murat O. Arcasoy	5405-275	8278

20792 7590 04/13/2006

MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER	
XIE, XIAOZHEN	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,137	ARCASOY ET AL.	
	Examiner	Art Unit	
	Xiaozhen Xie	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,7-9 and 17-24* is/are pending in the application.

4a) Of the above claim(s) *20-24* is/are withdrawn from consideration.

5)☒ Claim(s) *1,2 and 7-9* is/are allowed.

6)☒ Claim(s) *17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07/23/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

Applicant's amendment of the claims filed 30 January 2006 has been entered.

Election/Restrictions

Claims 1, 2 and 7-9 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 17-19, directed to the process of using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Claims 17-19 are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Claims 1, 2, 7-9, 17-24 are pending. Claims 3-6 and 10-16 are cancelled. Claims 20-24, which are directed to a method of screening a subject for cancer comprising detecting a protein, are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention of a method of using a polypeptide, there being no allowable generic or linking claim. Claims 1, 2, 7-9 and 17-19 are under examination.

Claim Rejections Withdrawn

The objections of claim 1 are withdrawn in response to Applicant's amendments to delete the non-elected species, and to correct the improper Markush language.

The rejection of claims 9 under 35 U.S.C. 112, first paragraph, as lacking enablement for host cells in the context of transgenic animals or gene therapy, is withdrawn in response to Applicant's amendment to add the limitation wherein the host cells are isolated.

The rejection of claims 1, 2 and 7-9 under 35 U.S.C. §112, second paragraph, as being indefinite for the recitation "a nucleic acid that encodes the opposite strand of a nucleic acid", is withdrawn in response to Applicant's amendment of the claims as "a nucleic acid that is the full length complement of SEQ ID NO: 4".

Rejections Maintained/New Grounds of Rejections

The Objections to the title and the abstract are maintained for reasons set forth in the previous office action (28 October 2005).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are directed to a method of screening a subject for cancer, comprising detecting the presence of the nucleic acid of SEQ ID NO: 4, and the presence of such a nucleic acid indicating that the subject is afflicted with or at risk of developing cancer. The specification teaches the isolation of EpoR splice variants, including EpoR Isoform 1 (SEQ ID NO: 4), from human cervix, breast, prostate, and ovarian cancer cell lines. The specification describes Isoform 1 as a truncated (EpoR-T) form, and possessing the extracellular and transmembrane domains of the wildtype receptor, while lacking portions of the cytoplasmic domain (pp. 11, Example 2). The specification, however, does not teach how to use the nucleic acid molecule (SEQ ID NO: 4) to detect cancer in a subject afflicted with or at risk of developing cancer. The claims recite that the detecting step is carried out by collecting a biological sample from the subject, and the specification defines a biological sample is from patient cells and/or cancer cells, including but not limited to breast, colon, lung, ovary, and prostate cells or cancer cells (pp. 8, lines 19, pp. 9, lines 14-15). There is no teaching in the specification as to the correlation between the presence of EpoR Isoform 1 and occurrence of any type of cancer using a cell sample accessible without aggressive surgical procedure, for example, how to screen an individual at risk of developing cancer by detecting the presence of EpoR Isoform 1 in the individual's lung cells? Further, the specification does not identify EpoR Isoform 1 expression in cancer patients, all that provided is the presence of EpoR isoforms in cultured cancer cells. A discrepancy between cultured cells and an in vivo system is reflected in the publication (Arcasoy et al., Biochem. Biophys. Res. Commu., 2003, 307:999-1007) showing that EpoR Isoform 1, while is

expressed in a colon cancer cell line, is not present in a primary colon cancer (pp. 1005, Fig. 5). Therefore, a method based on the assertion that EpoR Isoform 1 is present in certain cancer cell lines, and can be used to detect cancer in any individual with or without the disease, is insufficient in enabling one of skill in the art to practice the invention as claimed in the absence of supporting evidence or working examples.

Due to the large quantity of experimentation necessary to examine all tissues or cells in individuals with or without cancer for the presence of EpoR Isoform 1 transcript, and determine whether the individual is afflicted with or at risk of developing cancer, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art establishing that EpoR1 Isoform 1 expressed in cultured cancer cells, is not always expressed in primary tumors, and the breadth of the claim which encompasses all individuals and using all types of tissues/cells, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Conclusion

Claims 17-19 are rejected.

Claims 1, 2, 7-9 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie, Ph.D whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph.D. can be reached on 571-272-0867. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

Xiaozhen Xie, Ph. D.
April 6, 2006